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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/519,167

03/21/2006

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EXAMINER

DO, PENSEE T

ART UNIT

PAPER NUMBER

1641

MAIL DATE

DELIVERY MODE

12/21/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/519,167	Applicant(s) KILAAS ET AL.	
	Examiner Pensee T. Do	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 December 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13, 15-45 and 47-55 is/are pending in the application.
- 4a) Of the above claim(s) 22-45 and 47-55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 and 15-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-13, 15-45 and 47-55 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>December 13, 2010</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

This application 10519167, filed 03/21/2006 is a national stage entry of PCT/IB03/02994, International Filing Date: 07/01/2003 and claims foreign priority to 0215185.0, filed 07/01/2002.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 13, 2010 has been entered.

Amendment Entry & Claims Status

The amendment filed on December 13, 2010 has been acknowledged and entered.

Claims 1-13, 15-45, 47-55 are pending. Claims 14 and 46 are cancelled.

Claims 22-45, 47-55 are withdrawn from further consideration due to a restriction requirement.

Claims 1-13, 15-21 are being examined.

Information Disclosure Statement

The IDS submitted on December 13, 2010 has been acknowledged and considered.

Affidavits or Declaration under 37 CFR 1.132

The affidavit filed on December 13, 2010 has been acknowledge and entered. Please see discussion on the Response to Arguments section below.

Claimed Invention

1. (Currently Amended) Magnetic particles capable of binding a nucleic acid, the magnetic particles comprising a magnetic material and a matrix material, wherein the magnetic material is remanent upon exposure to a magnetic field such that the particles form aggregates when suspended in a liquid phase in the absence of a magnetic field but are dispersible upon application of a force to disrupt the aggregates, and the matrix material has a surface comprising functional groups which promote disaggregation of the particles in the presence of a liquid phase.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

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only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-9, 11, 13, 15-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Weitschies et al. (US 6,027,946).

Weitschies teaches magnetic particle comprising a magnetic material and a matrix/shell comprising functional groups such as aldehyde, thiol. (see col. 7, lines 34-38; col. 5, lines 45-60). Since Weitschies teaches the magnetic particles are ferrimagnetic or ferromagnetic which is the same material made up of the claimed magnetic particles, the magnetic particle in Weitschies is remanent upon exposure to a magnetic field such that the particles form aggregates when suspended in a liquid phase in the absence of a magnetic field but are dispersible upon application of a force to disrupt the aggregates. Since Weitschies teaches that the matrix comprises functional groups such as aldehyde or thiol groups which are the same as claimed in the present invention, the functional groups on the particles of Weitschies should promote disaggregation of the particles in the presence of a liquid phase.

For claims 2-4 and 6, Weitschies teaches the magnetic material comprises ferromagnetic or ferrimagnetic material a magnetic metal oxide such as iron oxides (see col. 7, lines 19-23).

For claim 5, Weitschies teaches the magnetic material is also magnetite. (see example 1).

For claim 7, Weitschies teaches the size of the magnetic particles ranges from 1nm to 1000 nm which is 0.0001 to 100 microns.

For claim 8, Weitschies teaches the particles are spherical by mentioning about the diameter of the particles (see col. 3, line 27).

For claim 9, Weitschies teaches the shell comprises of a polymer. (see col. 7, lines 33-37).

For claim 11, Weitschies teaches using dextran (polymer) coated magnetite particles (see example 1). Dextran is a hydrophilic polymer.

For claims 13, 15-18, Weitschies teaches the matrix comprises a structure specific substance (refers to the affinant in the present invention), which comprises of a nucleic acid, or antibodies (capable of binding to antigen=protein), biotin, oligonucleotide, DNA, RNA (see col. 5, lines 29-40; col. 9, lines 1-10).

For claim 19, Weitschies teaches that the invention is used in bacteriology, toxicology, infectiology and pathology analysis. (see col. 6, lines 8-11). Bacteriology or pathology detects microbial organism and thus requires a microbial protein or cell to bind to the microbial target organism.

Claims 1-13, 15-19, 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Rohr (US 5,445,970).

Rohr teaches magnetic label comprising magnetic core dispersed in a polymeric matrix. (see col. 10, line 1-30, table 1). The magnetic matrix also has functional groups such as aldehydes, carboxylic, epoxide, sulfhydryl, hydroxyl, amino, etc. (see col. 13,

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lines 42-65). Since Rohr teaches the magnetic particles are ferrimagnetic or ferromagnetic which is the same material made up of the claimed magnetic particles, the magnetic particle in Rohr is remanent upon exposure to a magnetic field such that the particles form aggregates when suspended in a liquid phase in the absence of a magnetic field but are dispersible upon application of a force to disrupt the aggregates. Since Rohr teaches that the matrix comprises functional groups such as aldehyde or thiol groups which are the same as claimed in the present invention, the functional groups on the magnetic particles of Rohr should promote disaggregation of the particles in the presence of a liquid phase.

For claims 2-6, Rohr teaches that the magnetic material comprises of a metal oxide such as iron oxide, and that the magnetic material is ferromagnetic or ferrimagnetic, such as magnetite (see col. 10, lines 1-28).

For claims 7 and 8, Rohr teaches the magnetic particles are spherical and have diameter ranging from 0.01 microns to 1000 microns. (see col. 12, lines 55-65).

For claims 9, 10, Rohr teaches that the magnetic particles has coating comprising of a polymer or a silica-based polymer (see col. 12, lines 43-54; col. 14, lines 33-55).

For claims 11, 12 and 21, since Rohr teaches using the same functional groups as those claimed by the present invention, i.e. carboxylic, amine, hydroxyl, etc., these functional groups can be hydrophilic or hydrophobic and are usable in non-polar or polar liquid. Rohr also teaches detecting microorganism target. (see col. 5, lines 53-54).

For claims 13, 15-19, Rohr teaches the magnetic particles are derivatized with a binding member for binding to a target, i.e. nucleic acid, or cell such as a microorganism. Such binding member comprises an antibody, avidin, biotin, oligonucleotides. (see col. 5, line 15-col. 16, line 23).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Weitschies or Rohr in view of Nelson et al. (US 5,962,641).

Weitschies and Rohr have been discussed above but fail to teach the target comprises a metal and the affinant comprises a chelator for the metal.

Nelson teaches that it is well known in the art that several different metal chelating ligands have been employed in immobilized metal ion affinity chromatography (IMAC) to purify proteins. (see col. 1, lines 20-25). Nelson also discloses a novel metal

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chelating complex for purifying recombinant proteins having a polyhistidine tail or tag.

(See col. 4, lines 18-22).

It would have been obvious to one of ordinary skills in the art to use appropriate binder for the analytes being detected, i.e. chelator to detect metal as taught by Nelson, since Weitschies and Rohr all require a binder/structure specific substance on their nanoparticles to detect analytes.

Response to Arguments

Applicant's arguments filed December 13, 2010 have been fully considered but they are not persuasive.

Regarding the rejection under 102 (b) by Weitschies et al, Applicants argue that Weitschies only teaches superparamagnetic which is not remanent upon exposure to a magnetic field.

This is not found persuasive because Weitschies teaches that the magnetic particles comprise ferromagnetic or ferrimagnetic material (see col. 7, lines 19-23) which is the same material recited in the claims. Furthermore, ferromagnetic or ferrimagnetic materials are known to exhibit magnetic moment or magnetism in the absence of a magnetic field. Therefore, there must be remnance in the ferromagnetic or ferromagnetic materials.

Applicants and the declaration under 37 CFR 1.132 state that the magnetic particles used by Weitschies are superparamagnetic and are not remnant upon exposure to a magnetic and aggregate after the removal of the magnetic because:

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1/. Weitschies teaches that the magnetic particles are freely movable because remanent particles aggregate in a liquid phase and as such are not freely movable.

2/. Weitschies uses dextran-coated magnetic material brought from Meito Sangyo which states from their website these particles are superparamagnetic.

This is not found persuasive because:

1/. ferromagnetic particles can be freely movable if they have not been exposed to a magnetic field.

2/. The examples only illustrate certain embodiments but not all embodiments of the invention in Weitschies.

Furthermore, Weitschies teaches that the ferromagnetic/ferrimagnetic particles which have a longer Neelian relaxation of magnetization, i.e. over 100 seconds. (col. 10, lines 9-10). Thus, the magnetic particles in Weitschies must have remnance of longer than 100 seconds after the magnetic field is turned off. As long as the ferrimagnetic/ferromagnetic magnetic particles in Weitschies have remnance, regardless of how long, they satisfy the requirement of the presently recited claims.

Regarding the rejection under 102 (e) by Tan et al, Applicants argue that Tan fails to teach a particle having both the required magnetic material and the required matrix material and submit that Tan, in a few variations, discloses particles with cores that can be magnetic (see col. 2, lines 27-29). Applicants also argue that Tan teaches superparamagnetic instead of ferromagnetic material.

This is found persuasive and therefore Tan is withdrawn herein.

Regarding the rejection under 102 (b) by Rohr, Applicants argue that Rohr teaches using a magnetic field on a magnetic label which displays a resultant force or movement. The extent of force or movement is modulated by an analyte that may be present in the test sample. This method works in a manner similar to that of Weitschies.

Regardless of the method of using the particles, Rohr teaches ferromagnetic/ferrimagnetic material such as magnetite (see col. 10, lines 1-28) which is the same material used in the present invention. Therefore, Rohr anticipates the present invention.

Regarding the 103(a) rejection for claim 20, Applicants use the same arguments for the primary references, Weitschies, Tan and Rohr. These arguments have been addressed above and therefore, no further discussion is necessary.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 571-272-0819. The examiner can normally be reached on Monday-Friday, 9-5.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Pensee T. Do/
Examiner, Art Unit 1641
/Jacob Cheu/
Primary Examiner, Art Unit 1641